REMARKS

Claims 1, 11-16, 28, 29, 37-39, and 42 were rejected. Claims 21, 22, and 24-26 were acknowledged as being allowable. Similarly, Claims 27, 30, and 31 were acknowledged as being allowable if they were formatted as an independent claim. As a result of the amendments herein, Claims 1, 12-16, 21, 22, 24-28, 31, and 42 are pending in the application.

In The Claims

Claim 1 has been amended by importing the compounds from Claim 37, which is rendered redundant by this amendment has been canceled herein. Claim 1 has also been amended by deleting the phrase "a disease involving cell hyperproliferation" and replacing it with "cancer." Support for this amendment can be found in Claim 11, which is rendered redundant by this amendment and has been canceled herein. The dependancies of Claims 12, 14, 16, and 42 have also been updated as a result of canceling Claim 11. Claim 1 was also amended to recite that the subject was "a subject with cancer." Support for this amendment can be found at page 24, lines 9-11.

Claim 27 was amended to correct a typographical error; Hin 1 was replaced by Hint1.

Claim 28 has been amended by importing the limitations from allowed Claim 30. As a result, Claims 29 and 30 have been canceled. Claims 38 and 39 have also been canceled.

By these amendments, no new matter has been added. Applicants respectfully request that examination continue on the claims as amended herewith.

Response to Objections

Claim 27 was objected to do a typographical error. This error has been corrected by the amendment herein.

Response to Rejections Under 35 U.S.C. § 112, 1st ¶

The Office Action rejected Claim 37 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement, in that the claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner alleged that the claimed method of treating a subject for cancer or a hyperproliferative disorder by administering IBT13131 or IBT4664 is not enabled. Again, Applicants submit that this rejection is in error.

In this rejection, the Examiner continued to require human clinical trials be conducted before a claim to a method of treatment will be deemed enabled. That, of course, is not the law. The Examiner has apparently confused the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption. So the Examiner's requirement for the Applicant to provide "pharmacodynamics and pharmacokinetics" data is not required for patentability. The correct standard for enablement was in fact cited, though not applied, in the current and previous Office Action: it is "undue experimentation."

Applicant has disclosed the two compounds recited in Claim 37 and shown that they are active against HeLa (cervical cancer cell line). Further, Applicants have tested the two recited compounds in T24 (bladder carcinoma), Saos2 (osteosarcoma), T98G (glioma), HCT116 (colon cancer); and Du145 (prostrate cancer) cell lines. At 10 μM the compounds reduce the colony forming units by more than 50%, indicating activity against a range of different carcinoma and sarcoma cell lines. Further, IBT13131 and IBT14664 had IC_{50} values of 11.7 and 9.5 μM, respectively, against K562, a leukemia cell line. These data can be presented in an Inventor Declaration should the Examiner require it. But to summarize, the compounds recited in Claim 37 are effective, and have been demonstrated as such, against a range of cancer cell lines.

Thus the appropriate question is whether a method of treating a subject with cancer by administering the recited compounds requires undue experimentation. It would not. But the Examiner cites Mohanlal to support that it would. Mohanlal teaches that there is a high failure rate in clinical trials, particularly phase II and III trials, because of the poor predictive value of *in vitro* screening technologies. This is generally true, though not always—the Orange Book is filled with examples where it was not true. And besides, Mohanlal is not relevant. Applicants claims do not recite a method of successfully conducting phase II or III clinical trials. So the fact that sometimes *in vitro* tests may not predict success in clinical trials (from Mohanlal or elsewhere), does not mean a method of treatment claim whereby one of two compounds are administered to a subject would require undue experimentation. This rejection is therefore not based on a proper application of the law of enablement and should be withdrawn.

Claims 1, 11-16, 39, and 42 are rejected under 35 U.S.C. 112, 1st ¶, as failing to comply with the written description requirement. Specifically, the Examiner objected to the deletion of the phrase "inhibiting the interaction between Hec1 protein and at least one further protein." This phrase described the mechanism of action of the recited compounds, not how or to whom it was administered. Applicants described in detail the mechanism, the mode of administration, the disease states, etc. in the description. So it is not clear then how the removal of the phrase relating to the mechanism would expand the claims outside of the disclosure. But in any event, to advance prosecution of this application, Applicants have added the phrase back into the claim. Based on the Examiner's comments, this amended is believed to therefore address this rejection.

Rejection Under 35 U.S.C. § 102

The Office Action rejected Claims 1, 11-16, 38, 39, and 42 under § 102(a) as allegedly being anticipated by Koshio *et al.* (WO02/062775) as evidenced by its English counterpart (U.S. 2004/077697). Specifically, the Examiner asserted that Koshio *et al.* discloses the administration of compositions of 3,5-dimethoxy-N-(5-morpholin-4-yl-4-phenylthiazol-2-yl)benzamide, N-[5-(4-cyclohexylpiperazin-1-yl)-4-(4-fluorophenyl)thiazol-2-yl]-2-methoxyisonicotinamide, or 3-chloro-N-[5-(4-cyclohexylpiperazin-1-yl)-4-(4-fluorphenyl)thiazol-2-yl]-4-hydroxybenzamide for treating thrombocytopenia. The composition Claims 38 and 39 have been canceled herein. Thus, this rejection is moot in regard to those claims. For the remaining claims (i.e., Claims 1, 12-16, and 42), these recite methods of treating cancer. Koshio *et al.* does not mention cancer or any other type of hyperproliferative disorder. Thus, Claims 1, 12-16, and 42 are novel over this reference.

The Examiner seem to disagree and felt that the phrase "thereby lessening cell hyperproliferation" did not impart patentable weight. This phrase was therefore deleted from the claim. But Claim 1 also recites administering the compounds "to a subject with cancer." Koshio *et al.* does not disclose this feature since the only subjects taught in this reference are those with thrombocytopenia.

It is also important to note that the Examiner's suggestion that practicing the method of Koshio *et al.* "will inherently be a method for treating cell hyperproleration and various cancers" is legally flawed. For a reference to inherently disclose a feature, that feature must necessarily be

present in the reference. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (a claim element is not "inherent" in the disclosure of a prior art reference unless evidence clearly shows that the missing descriptive matter is necessarily present in the thing described in the reference . . . [inherency] may not be established by mere probabilities or possibilities"). In this case, for the Examiner's position to be proper it must be necessarily true, and not just possible or even probable, that Koshio *et al.* disclose a method of treating a subject with cancer. Such a proposition is unsupportable since it is not inevitable that subjects with thrombocytopenia likewise have cancer.

Similarly, Claims 1, 11-16, and 38 were rejected under § 102(b) as allegedly being anticipated by Kinoshita *et al.* (U.S. 5,112,867). As disclosed above, Claim 38 was canceled, and the remaining claims (*i.e.*, Claims 1 and 12-16) recite methods of administering the compounds to a subject with cancer. In contrast, Kinoshita et al. discloses the treatment of only osteoporosis. Caner or any other hyperproliferative disorders is not mentioned at all in Kinoshita et al. Thus, for the same reasons above, Kinoshita et al. does not anticipate, either expressly or inherently, the method recited in Claims 1 and 12-16.

The Office Action then rejected Claims 28 and 29 under § 102(b) as allegedly being anticipated by Clark *et al.* (WO98/45433). The Examiner stated, however, that Claim 30 would be allowable if it were written as an independent claim or, in other words, amend Claim 30's base Claim 28 to include the limitations of Claim 30. This is what Applicants have done herein. Thus, the limitations of allowable Claim 30 have been imported into Claim 28, and this rejection is therefore believed to be overcome.

CONCLUSION

Enclosed herewith is payment in the amount of $65.00 under 37 C.F.R. § 1.17(a)(1) for a One-Month Extension of Time (Small Entity) and the $405.00 under 37 C.F.R. § 1.17(e) for the Request for Continued Examination. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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